

CDC Human Subjects Unanticipated Problem/Breaches of Protocol Report
(To Be Filled Out By Lead CDC Investigator)

Breaches in protocol and unanticipated problems include, but are not limited to, breakdowns in the consent process, violations of confidentiality of the data, and complaints by participants. Serious events should be reported to the IRB within 24 hours. Less serious events must be reported to the IRB within two weeks of their occurrence.

Please complete and sign this form. Submit to the Human Subjects Manager, Mark Long, at Mailstop D-50. Following review by the IRB, the IRB Chair will notify the Deputy ADS, who will notify OPRR in writing of the event and the corrective actions taken.

CDC Investigator: _____

Protocol Number: _____

Participant's I.D. (if available): _____

Date of Problem/Breach: _____ **Date First Known to You:** _____

Describe in detail the nature of the breach or unanticipated problem and timing of the event (attach addendum if necessary):

Event appears to be:

_____ Directly related _____ Indirectly related _____ Not related to research

Describe impact on participant:

Describe corrective action taken by study investigator: (Check all that apply)

- ☐ Stop enrollment of new participants
- ☐ Halt the study
- ☐ Change data management/ coding procedures
- ☐ Form committee to review procedures
- ☐ Other (Please Comment)

Does this event require revision to the (YES or NO):

☐ Protocol

☐ Consent
Form

If yes, please submit amendment (CDC form 1252), revised protocol and consent form.

Signature of lead CDC investigator: _____ Date: _____ _____		
Printed name of lead CDC investigator: _____ Phone: _____		
Approvals (Signature and Position Title)	Date:	Remarks:
Branch Chief:		
Division Director:		
CIO HSC:		